

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mel Epstein and Kjesten A. Wiig

Application No.: 10/003,740 Group Art Unit: 1614

Filed: October 31, 2001 Examiner: Kwon, Brian Yong S.

Confirmation No.: 2709

Title: METHODS AND COMPOSITIONS FOR REGULATING MEMORY
CONSOLIDATION

HAND DELIVERY

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- [] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- [] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- [] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

[X] Enclosed herewith is form PTO-1449:

- [X] Copies of the cited references (AA2-AK2, AA3-AC3, AL2-AQ2, AL3-AM3, AY2-AZ2, AR3-AZ3, AR4-AZ4, AR5-AZ5, AR6-AZ6, AR7-AZ7, AR8-AZ8, AR9-AZ9, AR10-AZ10, AR11-AZ11, AR12-AZ12, AR13-AZ13, AR14-AZ14, AR15-AZ15, AR16-AZ16, AR17-AZ17, AR18-AZ18, AR19-AZ19 and AR20) are enclosed.
- [] Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- [X] The listed references, AF2-AG2, AL2-AQ2, AL3-AM3, AU19-AZ19, and AR20 were cited in the enclosed Invitation to Pay Additional Fees, which contains results of a partial International Search in a counterpart foreign application. The remaining references cited in the Invitation to Pay Additional Fees have been listed in previously filed Information Disclosure Statements.
- [X] The "concise explanation" requirement (non-English references) for reference AM2 under 37 CFR 1.98(a)(3) is satisfied by:
 - [] the explanation provided on the attached sheet.
 - [] the explanation provided in the Specification.
 - [X] submission of the enclosed International Search Report.
 - [] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - [] the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 10/444,970, by Mel H. Epstein and Kjesten A. Wiig, filed May 23, 2003, Docket No.: 3474.1001-006

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ Examiner

____ Date

[X] A copy of each above-cited application, including the current claims, is enclosed.

[] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[X] Please charge Deposit Account 08-0380 in the amount of \$180.00. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: September 4, 2003

PATENT COOPERATION TREATY

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INVITATION TO PAY ADDITIONAL FEES

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-49 (partially), 50 (entirely), 51-52 (partially), 53-54 (entirely), 55-75 (partially), 76 (entirely), 77-78 (partially), 79 (entirely), 88-90 (entirely)

A use and pharmaceutical kit or preparation for enhancing memory or for treating or preventing amnesia or learning disabilities or for treating or preventing memory impairment in an animal susceptible to or suffering from a psychiatric disorder, selected from anxiety, depression or schizophrenia.

2. Claims: 1-49 (partially), 51-52 (partially), 55-75 (partially), 77-78 (partially)

A use and pharmaceutical kit or preparation comprising one or more amphetamine compound(s) for treating or preventing memory impairment in an animal susceptible to or suffering from age-associated memory impairment, minimal cognitive impairment, dementia, memory impairment associated with toxicant exposure, brain injury, brain aneurysm, Parkinson's disease, head trauma, Huntington's disease, Creutzfeldt-Jacob disease, stroke, epilepsy, mental retardation, Alzheimer's disease, age or AIDS-related dementia.

3. Claims: 1-49 (partially), 51-52 (partially), 55-75 (partially), 77-78 (partially)

A use and pharmaceutical kit or preparation comprising one or more amphetamine compound(s) for treating or preventing memory impairment in an animal susceptible to or suffering from Pick's disease.

4. Claims: 1-49 (partially), 51-52 (partially), 55-75 (partially), 77-78 (partially)

A use and pharmaceutical kit or preparation comprising one or more amphetamine compound(s) for treating or preventing memory impairment in an animal susceptible to or suffering from attention deficit disorder or attention deficit hyperactivity disorder.

5. Claims: 24-47 (partially)

Use of an amphetamine compound in the manufacture of a medicament for prophylaxis or treatment of an animal susceptible to or suffering from anxiety, depression,

INVITATION TO PAY ADDITIONAL FEES

minimal cognitive impairment, dementia, brain injury, brain aneurysm, Parkinson's disease, head trauma, Huntington's disease, Pick's disease, Creutzfeldt-Jacob disease, stroke, schizophrenia, epilepsy, mental retardation, Alzheimer's disease, age, attention deficit disorder, attention deficit hyperactivity disorder or AIDS-related dementia, as far as diminished memory is not a symptom.

The first problem underlying the present application is to provide an alternative means for enhancing (long-term) memory and for treating or preventing amnesia or learning disabilities and for treating or preventing memory impairment. The proposed solution is the use of an amphetamine compound.

The second problem underlying the present application is to provide an alternative means for the prophylaxis or treatment of an animal susceptible to or suffering from anxiety, depression, minimal cognitive impairment, dementia, brain injury, brain aneurysm, Parkinson's disease, head trauma, Huntington's disease, Pick's disease, Creutzfeldt-Jacob disease, stroke, schizophrenia, epilepsy, mental retardation, Alzheimer's disease, age, attention deficit disorder, attention deficit hyperactivity disorder or AIDS-related dementia, as far as diminished memory is not a symptom. The proposed solution is the use of an amphetamine compound.

Thus, in the context of the alleged invention, the use of an amphetamine in for the treatment of behavioral or neurological diseases or Pick's disease (having memory impairment as a symptom or not) is the alleged contribution over the prior art and the special technical feature which may, a priori, unify the plurality of different inventions.

The idea to use amphetamines for the treatment of behavioral or neurological diseases or Pick's disease has been previously disclosed. See for example US4034113, which discloses the use of amphetamine derivatives for the treatment of geriatric patients suffering from chronic organic brain disease and Parkinsonism (column 1, line 65 - column 3, line 2; column 3, lines 42-58; column 5, lines 13-18; column 5, line 57 - column 6, lines 26).

Therefore, the idea to use amphetamines in the treatment of behavioral or neurological diseases or Pick's disease is not novel and cannot be considered as the special technical feature which may unify the plurality of different inventions. No further technical feature(s) can be identified which may be regarded as a "special technical feature" involved in the technical relationship between the different (groups of) inventions. Therefore, two groups of inventions have been defined, relating to the first and second problem, respectively, as defined above.

With respect to the first group of inventions (first problem), the use of an amphetamine for enhancing (long-term) memory and for treating or preventing memory impairment is the alleged contribution over the prior art and the special technical feature which may, a priori, unify the plurality of different inventions, in particular the

treatment of memory impairment in the specific patients claimed.

However, the idea to use amphetamines for enhancing (long-term) memory and for treating or preventing memory impairment is already known from the prior art. For example, Soetens et al. disclose in Psychopharmacology, 119(2), 155-162, 1995 that d-amphetamine enhances long-term retention in humans, leaving the short-term memory unaffected (abstract; p. 156, right-hand column, par. 1; p. 160, right-hand column, par. 2 - p. 161, left-hand column, par. 1).

Reus et al. state in Biological Psychiatry, 14(2), 345-356, 1979 that intravenous d-amphetamine improves memory and memory consolidation in depressed patients (abstract; p. 346, par. 3-4; p. 348, par. 4; p. 353, par. 2 - p. 354, par. 2).

Therefore, the idea to use amphetamines for enhancing (long-term) memory and for treating or preventing memory impairment is not novel and cannot be considered as the special technical feature which may unify the plurality of different inventions. No further technical feature(s) can be identified which may be regarded as a "special technical feature" involved in the technical relationship between the different (groups of) inventions.

Consequently, the present application lacks unity of invention and the different solutions not belonging to a common inventive concept are detailed as the different subjects listed above.

The first group of inventions, relating to the first problem, has been further subdivided based on the specific patient. Each of the inventions listed is a distinct invention, characterised by its own special technical feature, defining the contribution which each of the claimed inventions makes over the prior art.

As searching the further inventions would have caused a major additional searching effort, only the first invention was searched.

The application relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT. They have been divided as defined above. If the applicant pays additional fees for one (or more) not yet searched group(s) of invention(s), then the further search(es) may reveal further prior art that gives evidence of a further lack of unity 'a posteriori' within one (or more) of the not yet searched group(s). In such a case only the first invention in this (each of these) group(s) of inventions, which is considered to lack unity of invention, will be the subject of a search.

No further invitation to pay further additional fees will be issued. This is because Article 17(3)(a) PCT stipulates that the ISA shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims ('main invention') and for those parts which relate to inventions in respect of which the additional fees were paid. Neither the PCT nor the PCT guidelines provide a legal basis for further invitations to pay further additional search fees (W17/00, point 11 and W1/97, points 11-16).

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Although claims 55-78 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Further defect(s) under Article 17(2)(a):

Continuation of Box 3.

Claims Nos.: 80-87

Present claims 4, 7-12, 14-17, 22, 24, 27-50, 55-78, 88-90 relate to compounds which are actually not well-defined. The use of the definitions "a metabolite or prodrug" (claims 4, 7-12, 24, 27-50, 56, 59-78, 88-90), "eutomer or distomer" (claims 14-17, 37-40, 55-78), "a neuronal growth factor", "a neuronal survival factor", "a neuronal trophic factor", "a cholinergic modulator", "an adrenergic modulator", "a nonadrenergic modulator", "a dopaminergic modulator", "a glutaminergic modulator", "an agent that stimulates the PKC, PKA, GABA, NMDA, cannabinoid, AMPA, kainate, PDE, CREB or nootropic pathways" (claims 22, 45, 71) in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. The lack of clarity is such as to render a meaningful complete search impossible.

In addition, claims 1-7, 12-27, 32-50, 55-59, 79 and 88-90 relate to a very large number of possible compounds. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Moreover, claims 80-87 relate to a method of doing business, which the International Searching Authority is not required, under the regulations, to search (Article 17(2)(a)(i) PCT and Rule 39(iii) PCT).

Consequently, the search for the first invention has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compounds specified in claims 8-11, 28-31, 51-54 and 60-63, optionally in combination with methylphenidate or the adrenergic modulators dopamine, norepinephrine or epinephrine (description p. 30, lines 21-31), and their use in enhancing long-term memory and in the treatment or prevention of amnesia or learning disabilities and in the treatment of memory impairment resulting from anxiety, depression and schizophrenia.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>YASAR S ET AL: "Are metabolites of L-deprenyl (selegiline) useful or harmful? Indications from preclinical research." JOURNAL OF NEURAL TRANSMISSION SUPPLEMENT, vol. 48, 1996, pages 61-73, XP008020416 ISSN: 0303-6995</p> <p>abstract</p> <p>page 61, paragraph 1</p> <p>page 68, paragraph 2 -page 70, paragraph 2</p> <p>page 71, paragraph 2</p> <p>---</p>	<p>1, 4-12, 14-20, 24-33, 37-43, 48-52, 55-69, 74-79</p>
X	<p>GELOWITZ DOUGLAS L ET AL: "Chronic L-deprenyl or L-amphetamine: Equal cognitive enhancement, unequal MAO inhibition." PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR, vol. 47, no. 1, 1994, pages 41-45, XP008020420 ISSN: 0091-3057</p> <p>abstract</p> <p>page 41, column 1, paragraph 1 -page 42, column 1, paragraph 1</p> <p>page 43, column 1, paragraph 4 -page 44, column 2, paragraph 1</p> <p>---</p> <p>-/-</p>	<p>1, 4-10, 12, 14-20, 24-30, 32, 33, 37-43, 48-52, 55-62, 64-69, 76-78</p>



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more others such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No

PCT/US 01/45793

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>SOETENS E ET AL: "Effect of amphetamine on long-term retention of verbal material." <i>PSYCHOPHARMACOLOGY</i>, vol. 119, no. 2, 1995, pages 155-162, XP008020419 ISSN: 0033-3158</p> <p>abstract page 156, column 1, paragraph 2 page 156, column 2, paragraph 1 page 160, column 2, paragraph 2 -page 161, column 1, paragraph 1 ---</p>	1,2, 4-10,12, 14-20, 47-50, 55-62, 64-69, 73, 76-78, 88-90
X	<p>GOLD P E ET AL: "MODULATION OF LONG-TERM POTENTIATION BY PERIPHERALLY ADMINISTERED AMPHETAMINE AND EPINEPHRINE" <i>BRAIN RESEARCH</i>, vol. 305, no. 1, 1984, pages 103-108, XP008020417 ISSN: 0006-8993</p> <p>abstract page 103, column 2, paragraph 1 page 104, column 2, paragraph 1 page 105, column 2, paragraph 2 page 106, column 2, paragraph 2 ---</p>	1,4-10, 14-21, 24-30, 32,33, 37-44, 48-50, 55-62, 64-70, 74-78
X	<p>REUS V I ET AL: "DEXTRO AMPHETAMINE EFFECTS ON MEMORY IN A DEPRESSED POPULATION" <i>BIOLOGICAL PSYCHIATRY</i>, vol. 14, no. 2, 1979, pages 345-356, XP008020409 EN ISSN: 0006-3223</p> <p>abstract page 346, paragraph 3 - paragraph 4 page 348, paragraph 4 page 353, paragraph 2 -page 354, paragraph 2 ---</p>	1,4-10, 12, 14-20, 24-30, 32,33, 37-43, 48,49, 55-62, 64-69, 74,75, 77,78

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Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/US 01/45793

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>KIRRANE RICHELLE M ET AL: "Effects of amphetamine on visuospatial working memory performance in schizophrenia spectrum personality disorder." NEUROPSYCHOPHARMACOLOGY, vol. 22, no. 1, January 2000 (2000-01), pages 14-18, XP001162739 ISSN: 0893-133X abstract page 15, column 2, paragraph 3 -page 16, column 1, paragraph 3 page 17, column 1, paragraph 2 - paragraph 3 ---</p>	1,2, 4-10, 18-20, 24-30, 32-34, 48,49,79
X	<p>BARCH D M ET AL: "The effects of D-amphetamine on language function in schizophrenia." SOCIETY FOR NEUROSCIENCE ABSTRACTS, vol. 23, no. 1-2, 1997, page 1952 XP001157878 27th Annual Meeting of the Society for Neuroscience; New Orleans, Louisiana, USA; October 25-30, 1997 ISSN: 0190-5295 the whole document ---</p>	1,4-10, 12, 14-20, 24-30, 32,33, 37-40, 48,49, 55-62, 64-66, 74,75, 77-79
X	<p>QUARTERMAIN D ET AL: "AMPHETAMINE ENHANCES RETRIEVAL FOLLOWING DIVERSE SOURCES OF FORGETTING" PHYSIOLOGY & BEHAVIOR, vol. 43, no. 2, 1988, pages 239-242, XP008020418 ISSN: 0031-9384 abstract page 239, column 1, paragraph 2 page 241, column 1, paragraph 2 -column 2, paragraph 2 ---</p>	1,4-10, 12-21, 24-30, 32,33, 37-40, 44,48, 49, 55-62, 64-66, 70,74, 75,77-79
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**Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No

PCT/US 01/45793

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	QUARTERMAIN D ET AL: "ALLEVIATION OF SCOPOLAMINE AMNESIA BY RETRIEVAL ENHANCING TREATMENTS" PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR, vol. 30, no. 4, 1988, pages 1093-1096, XP008020412 ISSN: 0091-3057 abstract page 1093, column 1 page 1095, column 1, paragraph 5 -column 2, paragraph 3 ---	1, 4-10, 12, 14-20, 24-30, 32, 33, 37-40, 48, 49, 55-62, 64-66, 74, 75, 77-79
X	US 5 422 355 A (WHITE JOHN F ET AL) 6 June 1995 (1995-06-06) column 3, line 51 -column 5, line 36 column 10, line 27 - line 34 column 11, line 21 - line 40 claims 1, 7 ---	1, 2, 4-6, 18-21, 24-26, 32-34, 44, 48-50, 76-79, 88-90
X	WO 99 16746 A (HOECHST MARION ROUSSEL INC) 8 April 1999 (1999-04-08) page 1, paragraph 1 -page 4, paragraph 9 page 9, paragraph 3 page 18, paragraph 4 page 23, paragraph 11 -page 24, paragraph 1 page 28, paragraph 2 -page 29, paragraph 2 claims 1, 3, 5, 114, 115, 170, 171 ---	1, 2, 4-7, 12, 18-21, 24-27, 32-34, 44, 48-50, 76, 79, 88-90
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**Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No

PCT/US 01/45793

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 17067 A (DISANTO ANTHONY R ; SOMERSET PHARMACEUTICALS INC (US)) 15 May 1997 (1997-05-15) page 1, line 10 - line 16 page 5, line 17 - line 32 page 6, line 22 -page 7, line 7 page 7, line 27 -page 8, line 2 examples 1-3 ---	1, 2, 4-6, 12, 14-21, 24-26, 32-34, 37-40, 44, 47-50, 55-58, 64-66, 70, 74-79, 88-90
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